



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alan R. Fritzberg et al.

Title: SKELETAL-TARGETED RADIATION TO TREAT BONE-ASSOCIATED PATHOLOGIES

Docket No.: 295.054US1

Filed: June 20, 2003

Examiner: Unknown

Customer No.: 21186

Serial No.: 10/601081

Due Date: N/A

Group Art Unit: Unknown

Confirmation No.:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

- ☒ A return postcard.
- ☒ A Supplemental Information Disclosure Statement (1 pg.), Form 1449 (1 pg.), and copies of 16 cited documents.
- ☒ Communication Concerning Co-Pending Applications (1 pg.).

If not provided for in a separate paper filed herewith, Please consider this a **PETITION FOR EXTENSION OF TIME** for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
Customer Number 21186

By: Warren D. Woessner  
Atty: Warren D. Woessner  
Reg. No. 30,440

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 11<sup>th</sup> day of September, 2003.

Dawn M. Poole  
Name

Dawn M. Poole  
Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. Customer Number 21186  
(GENERAL)



10/N 10/601,081

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alan R. Fritzberg et al. Examiner: Unknown  
Serial No.: 10/601,081 Group Art Unit: Unknown  
Filed: June 20, 2003 Docket: 295.054US1  
Title: SKELETAL-TARGETED RADIATION TO TREAT BONE-ASSOCIATED  
PATHOLOGIES

COMMUNICATION CONCERNING CO-PENDING APPLICATIONS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicant would like to bring to the Examiner's attention the following related co-pending applications in the above-identified patent application:

| <u>Serial No.</u> | <u>Filing Date</u> | <u>Attorney Docket</u> | <u>Title</u>   |
|-------------------|--------------------|------------------------|--|
| 10/014,335        | December 11, 2001  | 295.044US1             | HIGH DOSE RADIONUCLIDE COMPLEXES FOR BONE MARROW SUPPRESSION     |
| 10/159,245        | May 29, 2002       | 295.044US2             | HIGH DOSE RADIONUCLIDE COMPLEXES FOR BONE MARROW SUPPRESSION     |
| 10/172,363        | June 14, 2002      | 295.052US1             | SKELETAL TARGETED RADIATION TO TREAT BONE-ASSOCIATED PATHOLOGIES |

Respectfully submitted,  
ALAN R. FRITZBERG ET AL.  
By Applicants' Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6903

Date 9-11-03

By Warren D. Woessner  
Warren D. Woessner  
Reg. No. 30,440

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 11th day of September, 2003.

Dawn M. Poole  
Name

Dawn M. Poole  
Signature



10/601,081

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|             |  |                 |            |
|-------------|--|-----------------|------------|
| Applicant:  | Alan R. Fritzberg et al.   | Examiner:       | Unknown    |
| Serial No.: | 10/601,081   | Group Art Unit: | Unknown    |
| Filed:      | June 20, 2003  | Docket:         | 295.054US1 |
| Title:      | SKELETAL-TARGETED RADIATION TO TREAT BONE-ASSOCIATED PATHOLOGIES |                 |            |

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to MPEP 609, Applicants request that a copy of the Form 1449, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. § 1.97(b), no fee or statement is required with the Supplemental Information Disclosure Statement. However, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 19-0743 in order to have this Supplemental Information Disclosure Statement considered. The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,  
ALAN R. FRITZBERG ET AL.  
By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6903

Date 9-11-03

By Warren D. Woessner  
Warren D. Woessner  
Reg. No. 30,440

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Dawn M. Poore  
Name

Dawn M. Poore  
Signature

Substitute for form 1449A/PTO  
**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Use as many sheets as necessary)



Complete if Known

|                      |                 |
|----------------------|-----------------|
| Application Number   | 10/601,081      |
| Filing Date          | June 20, 2003   |
| First Named Inventor | Fritzberg, Alan |
| Group Art Unit       | Unknown         |
| Examiner Name        | Unknown         |

Sheet 1 of 2

Attorney Docket No: 295.054US1

### US PATENT DOCUMENTS

| Examiner Initial * | USP Document Number | Publication Date | Name of Patentee or Applicant of cited Document | Class | Subclass | Filing Date If Appropriate |
|--------------------|---------------------|------------------|---|-------|----------|----------------------------|
|                    | 4,897,255           | 01/30/1990       | Fritzberg et al.                                | 424   | 1.1      | 06/19/1987                 |
|                    | 5,393,512           | 02/28/1995       | Vanderheyden et al.                             | 424   | 1.53     | 09/20/1993                 |
|                    | 5,679,318           | 10/21/1997       | Vanderheyden et al.                             | 424   | 1.11     | 11/21/1994                 |
|                    | 5,756,685           | 05/26/1998       | Fritzberg et al.                                | 530   | 391.5    | 07/12/1996                 |

### FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Foreign Document No | Publication Date | Name of Patentee or Applicant of cited Document | Class | Subclass | T <sup>2</sup> |
|--------------------|---------------------|------------------|---|-------|----------|----------------|
|--------------------|---------------------|------------------|---|-------|----------|----------------|

### OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  |
|--------------------|--|
|                    | ANDERSON et al., "High-Dose Samarium-153 Ethylene Diamine Tetramethylene Phosphonate: Low Toxicity of Skeletal Irradiation in Patients with Osteosarcoma and Bone Metastases", <u>Journal of Clinical Oncology</u> , 20, 189-196 (2002).   |
|                    | BENSINGER et al., "166Ho-DOTMP and High-Dose Melphalan before Autologous Peripheral Blood Stem Cell Transplantation in Patients with Multiple Myeloma", Abstract P287; IXth International Workshop on Multiple Myeloma (2003).   |
|                    | BENSINGER et al., "Skeletal Targeted Radiotherapy (STR) with 166Ho-DOTMP plus Melphalan and Autologous Stem Cell Transplant (ASCT) in Multiple Myeloma(MM)", <u>Meeting Proceedings of ASCO</u> , 22, ASCO Annual Meeting, May 2003; Abstract Number 3346, 833 (2003).   |
|                    | BREITZ et al., "Dosimetry of High Dose Skeletal Targeted Radiotherapy (STR) with 166-Ho-DOTMP", <u>Cancer Biotherapy and Radiopharmaceuticals</u> , 18, 225-230 (2003).  |
|                    | DISPENZIERI et al., "A Phase I Study of a Conditioning Regimen for Peripheral Stem Cell Transplantation (PBSCT) for Multiple Myeloma (MM): 153Samarium Ethylenediaminetetramethylenephosphonate (153SM-EDMPT) and Melphalan", <u>Blood</u> , 96, Abstract 2397, 558a (2000).   |
|                    | DISPENZIERI et al., "A Phase I/II Dose Escalation Study of 153-Samarium EDTMP (153-Sm-EDMTP) with Fixed Dose Melphalan Peripheral Stem Cell Transplantation (PBSCT) for Multiple Myeloma (MM)", <u>Blood</u> , 98, Abstract 2855, 682a-683a (2001).  |
|                    | GIRALT et al., "166Ho-DOTMP Plus Melphalan Followed by Peripheral Blood Stem Cell Transplantation in Patients with Multiple Myeloma: Results of Two Phase I/II Trials", <u>Blood</u> , Blood First Edition Paper; DOI 10.1182/2002-10-3250, 1-38 (2003).   |
|                    | GIRALT et al., "Long-Term Follow-Up of 83 Patients with Multiple Myeloma (MM) Treated on a Phase I-II Study of Skeletal Targeted Radiotherapy (STR) Using 166Ho-DOTMP Plus Melphalan with or without Total Body Irradiation (TBI) and Autologous Hematopoietic Stem Cell ...", <u>Blood</u> , 100, 44th Annual Meeting of the American Society of Hematology; Abstract 670, 179a (2002). |
|                    | HOGAN et al., "Successful Treatment of POEMS Syndrome with Autologous Hematopoietic Progenitor Cell Transplantation", <u>Bone Marrow Transplantation</u> , 28, 305-309 (2001).   |

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Complete if Known

|                      |                 |
|----------------------|-----------------|
| Application Number   | 10/601,081      |
| Filing Date          | June 20, 2003   |
| First Named Inventor | Fritzberg, Alan |
| Group Art Unit       | Unknown         |
| Examiner Name        | Unknown         |

Sheet 2 of 2

Attorney Docket No: 295.054US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials* | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  |
|-----------------------|--|
|                       | RAJENDRAN et al., "High-Dose 166Ho-DOTMP in Myeloablative Treatment of Multiple Myeloma: Pharmacokinetics, Biodistribution, and Absorbed Dose Estimation", <u>J Nucl Med</u> , <u>43</u> , 1383-1390 (2002).   |
|                       | WISEMAN et al., "Bone Targeted Radioisotope Therapy for Treatment of Multiple Myeloma and Bone Tumors", <u>International Journal of Cancer</u> , <u>13</u> , Abstract O 109, 104 (2002).   |
|                       | WISEMAN et al., "Residual Whole Body 153Samarium Activity Predicts for Successful Autologous Peripheral Blood Progenitor Cell (PBPC) Engraftment Following High Dose 153Samarium Ethylene Diamine Tetramethylene Phosphonate (153Sm-EDTMP) Targeted Radiotherapy", <u>Blood</u> , <u>96</u> , Abstract 1811, 421 (2000). |

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached